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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/478,222 01/05/00 GARVEY

D 102258.346

EXAMINER

HM12/0322

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CELSEA, D  
ART UNIT

PAPER NUMBER

1627  
DATE MAILED:

03/22/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

File  
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# Office Action Summary

Application No.  
09/478,222

Applicant(s)  
Garvey et al.

Examiner  
Bennett Celsa

Group Art Unit  
1627



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 35-69 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 35-69 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

Claims 35-69 are currently pending.

#### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 35-42, drawn to compositions comprising NO containing compounds (nucleotides, proteins) for treating impotence, classified, in various classes/subclasses upon election of a compound including class 514 , subclass 2.
  - II. Claims 43-47, drawn to compositions comprising compounds inducing endogenous NO production (e.g. L-Arginine) for treating impotence, classified in various classes/subclasses upon election of compound, including class 514 , subclass 663.
  - III.. Claims 48-52, drawn to compositions comprising 2-hydroxy-2-nitrosohydrazine for treating impotence, classified in class 514, subclass 664.
  - IV.. Claims 53-56, drawn to compositions comprising (E)-alkyl-2-((E)-hydroximino)-5-nitro-3-hexene amine/amide, classified in class 514, subclass 611.
  - V.. Claims 57-60, drawn to compositions comprising a "sydnimine compound" for treating impotence, classified in class 514, subclass 403.
  - VI. Claims 61-65, drawn to compositions comprising S-nitrosothiol compounds for treating impotence, classified in various classes/subclasses upon election of a compound, including class 514, subclass 706.

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VII. Claims 66-69, drawn to compositions comprising NONOate compounds for treating impotence, classified in various classes/subclasses upon election of a compound, including class 514, subclass 778.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are directed to methods which require the use of bioactive compounds which differ in chemical structures and/or expectant properties and/or method of syntheses; which would necessitate different and separately burdensome manual/computer structure, bibliographic and classification searches. Additionally, the individual compounds utilized in these methods would be expected to have different modes of operation, different functions, and/or different effects .

3. Because these inventions are distinct for the reasons given above

- a. have acquired a separate status in the art as shown by their different classification
- b. require different and separately burdensome manual/computer searches; and
- c. have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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### **ELECTION OF SPECIES (Groups I-VII)**

The claims of the individual groups recited above are directed to methods of treating impotence using compounds which are patentably distinct from each other due to differences in chemical structures and/or expectant properties and/or method of syntheses; which would necessitate different and separately burdensome manual/computer structure, bibliographic and classification searches.

Applicant is required to elect a *single compound* from any one of Groups I-VII (whichever is elected above) to which the present application will be restricted to if a generic claim is not found to be allowable. The response **should also include a structural formula** corresponding to the elected species if not already present in the specification.

Applicant is advised that a response to the above election requirement should include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

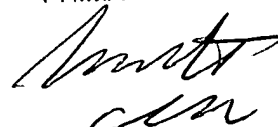
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)

March 21, 2001

**BENNETT CELSA  
PRIMARY EXAMINER**

  
3/21/01